the "level of cardiac output demanded by the body", for increasing and decreasing. The escape interval X (column 27, line 64-68)."

After more carefully reviewing the Zacouto specification, Applicant believes the above observation is erroneous. In Zacouto, the escape interval following a sensed beat, referred to as "Y" is determined as a function of a previous measurement of the distance between two heart contractions not separated by a paced beat. Although the Abstract of the invention describes this as the interval between "two consecutive spontaneous detected signals", this terminology is broad enough to include the interval between a paced beat and the next subsequent sensed beat. This is illustrated in FIG. 1, which refers to the measurement of the time between the paced beat and the next spontaneous beat as K1 or K2 and refers to the escape interval following the sensed beat as Y1 or Y2. Y varies as a function of K. As such, the escape interval following a sensed beat varies in response to the previously measured sensed beat, rather than in correlation with a measured physiological parameter indicative of physiological need for cardiac output. Applicant acknowledges that in column 27, lines 64-68, it states that the period X or the period Y/K may be modified in response to variation of intramyocardial pressure. However, Applicant notes that variation of the period X merely controls the escape interval following a paced beat. Claim 6 clearly requires a reset means for resetting the escape interval in response to a sensed heart beat, and means for adjusting the escape interval to provide pacing pulses <u>on demand at a minimum rate</u> correlated to the cardiac output requirements of the patient. Zacouto's device does not meet these claim limitations for a number of reasons.

The first reason that Zacouto does not meet these claim limitations is that the intracardiac pressure measured by Zacouto is not a parameter indicative of need for cardiac output. The

need for cardiac output varies over short periods of time, depending upon the load upon the heart at that particular time. In Zacouto, in column 28, lines 6-7, it is stated that the variation in intramyocardiac pressure is very slow and may be detected only after several hours in certain cases. As such, even if the rest of the claim limitations of claim 6 were met, it is clear that variation of the heart rate in response to this slow changing variable clearly will not provide a pacemaker which varies in response to physiologic need for heart output. As such, Zacouto is lacking the means for measuring a physiological parameter indicative of the level of cardiac output demanded by the patient's body and for providing an escape interval modifying signal, and similarly lacks means responsive to the escape interval modifying signal for adjusting the escape interval to provide pacing pulses on demand at a minimum rate correlated to the cardiac output requirements of the patient unreliant at a minimum rate correlated to the cardiac output requirements of the patient.

Second, even if the intramyocardiac pressure were a parameter indicative of the level of cardiac output demanded by the patient's body, Zacouto still lacks the "means responsive to the escape interval modifying signal for adjusting the escape interval to provide pacing pulses on demand at a minimum rate correlated to the cardiac output requirements of the patient". Claim 6 states that the "escape interval" is restarted upon a reset signal in response to a naturally occurring heart signal. As such, in order for Zacouto to meet claim 6, it would have to alter its escape interval following a sensed beat in correlation with the measured intramyocardiac pressure. Zacouto's device does not do this. The escape interval after a sensed beat in Zacouto is, as discussed above, a function of the previously measured K interval. Although Zacouto suggests in column 28, that the K to Y ratio might be

altered by the sensed intramyocardiac pressure, there is no suggestion therein that the basic operation of the device be changed. Zacouto's device varies the Y period widely, depending upon the measured K period, providing a Y period shorter than the K period in some circumstances and a Y interval longer than the K period in other circumstances. As long as this basic relationship between the K and Y interval persists in Zacouto's device, the Y escape interval cannot be varied to provide a minimum demand rate correlated to the intramyocardiac pressure. Instead, as Applicant noted in its previous Amendment, Zacouto discloses a device in which the escape interval after sensing varies in response to a previously measured escape interval, rather than in response to any physiologic demand. In essence, Zacouto suggests altering the ratio of K to Y, but does not suggest changing the underlying fact that Y correlates with K, not intramyocardial pressure.

Zacouto fails to meet the limitations of claim 6 because it does not provide means for measuring a physiological parameter indicative of the level of cardiac output demanded by the patient's body and does not provide a means for adjusting the escape interval to provide pacing pulses <u>on demand at a minimum rate</u> correlated to the cardiac output requirements of the patient, because it does not teach or suggest the alteration of the escape interval after a naturally occurring heart signal to provide an escape interval correlated to the cardiac output requirements of the patient. As such, Applicant respectfully asserts that claim 6 is clearly novel over Zacouto. Claims 7, 8 and 11, all including the limitations of claim 6 are similarly believed novel over Zacouto.

Claim 12 was rejected under 35 USC 103 as unpatentable over Zacouto in view of Greatbatch. In connection with this rejection, the Official Action states that "Employing a P-wave sensing with the Zacouto system is an obvious matter of choice of conventional

sensing circuitry to one of ordinary skill in the art in view of Greatbatch's teaching."

Although Applicant acknowledges that Greatbatch does disclose a P-wave sensor, Greatbatch clearly does not disclose the elements of claim 6, missing from Zacouto. As such, claim 12 is believed not to be obvious over Zacouto.

Finally, claims 9 and 10 were rejected under 35 USC 103 as obvious over Zacouto in view of Wirtzfeld. In connection with this rejection, the Official Action states that "Wirtzfeld et al show the conventional expedient of employing a blood molecular oxygen level chemical detector for use in adjusting the escape interval of a pacer. One of ordinary skill in art would find the use of such a detector to adjust the escape rate of the Zacouto pacer to be an obvious matter of selection or substitution of well-known parts."

Applicant acknowledges that Wirtzfeld does disclose an element of claims 9 and 10, not found in Zacouto, in that it discloses a means for detecting a blood chemical parameter indicative of need for cardiac output. However, claim 9 includes the limitation of claim 6 which requires a means for adjusting the escape interval to produce pacing pulses on demand at a minimum rate correlated to the cardiac output requirements of the patient, and means for restarting the escape interval following a sensed naturally occurring heart signal. As such, claim 9 like claim 6 requires the variation of the escape interval following a sensed electrical signal within the heart, in correlation with the cardiac output requirements of the patient. Clearly, Wirtzfeld does not include this claim element, in that it has no means for sensing naturally electrical signals occurring in the heart. As discussed above, Zacouto also lacks this claim element. As such, the two references together are not believed to make the subject matter of claim 9 and 10 obvious. Although it is suggested in the

rejection that by merely substituting Wirtzfeld's venous oxygen sensor for Zacouto's intramyocardiac pressure detector, one would have produced a device according to claim 9, this is simply not true. Mere substitution of Wirtzfeld's blood oxygen sensor would produce a device like Wirtzfeld's which changes its escape interval after pacing in response to measured changes in cardiac output requirements, but does not provide a means for providing pacing pulses on demand at a minimum rate correlated to the cardiac output requirements of the patient.

In view of the above arguments, all claims in the case are believed allowable over the art, as cited in the Official Action. Applicant requests reconsideration of the rejections in the Official Action, in light of the above arguments.

Respectfully submitted,

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